REMARKS/ARGUMENTS

The Pending Claims

Claims 1-5, 7-10, 12, 13, 16-22, and 40 are pending and are directed to a method of inducing an immunological response.

Amendments to the Claims

The claims have been amended to point out more particularly and claim more distinctly the invention. In particular, claim 4 has been amended to no longer recite the redundant "vector," and claim 17 has been amended to depend from claim 1.

No new matter has been added by way of these amendments to the claims.

Summary of the Office Action

The Office objects to claims 4 and 17-22.

The Office rejects claims 17-22 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

The Office rejects claims 1-5, 7-10, 12, 13, 16, and 40 under 35 U.S.C. § 103(a) as allegedly obvious over Schlom et al. (WO 00/34494) and Pecher (WO 01/24832).

These objections and rejections are traversed for the following reasons.

Discussion of the Claim Objections

The Office contends that claim 4 is indefinite since it contains a second occurrence of the term "vector" Claim 4 has been amended to remove the second occurrence of the term "vector."

The Office contends that claim 17 and claims 18-22 dependent thereon are indefinite because claim 17 depends on a canceled claim. Claim 17 has been amended to depend from claim 1.

Applicants believe that the claim objections are moot in view of the amendments to the claims.

Discussion of the Indefiniteness Rejections

The Office contends that claim 17 and claims 18-22 dependent thereon are indefinite for depending from a canceled claim. As discussed above, claim 17 has been amended to depend from claim 1. Applicants believe that the indefiniteness rejection is moot in view of the amendment to claim 17.

Discussion of the Obviousness Rejection

In response to Applicants' arguments, the Office maintains that the subject matter of the pending claims is obvious in view of the Schlom and Pecher references. The obviousness rejection is traversed for the following reasons.

The present invention, as defined by the pending claims, is directed to a method for inducing an immunological response against a cell expressing a breast cancer associated antigen in a human, wherein the method comprises (a) selecting a human having breast cancer or at risk for developing such a breast cancer tumor, (b) administering to the individual a first poxvirus vector containing one or more DNA segments that encode (i) mucin (MUC) or an antigenic portion thereof or modified version thereof and (ii) carcinoembryonic antigen (CEA) or an antigenic portion thereof or modified version thereof, and (c) at regular intervals thereafter administering at least a second poxvirus vector containing one or more DNA segments that encode (i) MUC or antigenic portion thereof or modified version thereof and (ii) CEA or an antigenic portion thereof or modified version thereof, such that an immunological response against the cell expressing the breast cancer associated antigen is induced in the individual.

The Office contends that the Schlom reference discloses a prime-boost protocol for the treatment or prevention of cancer, wherein viral vectors, such as poxvirus vectors, encode an antigen. The Office acknowledges that the Schlom reference does not disclose a poxvirus vector encoding MUC and CEA, let alone a prime-boost protocol employing *two* poxvirus vectors encoding MUC and CEA, as required by the pending claims. However, the Office contends that the Pecher reference discloses a pharmaceutical composition for treating and

preventing human tumors, which express CEA and/or MUC-1, and the use thereof as a vaccine for activating the immune system. In particular, the Office contends that the Pecher reference discloses the combined administration of vectors, including vaccinia virus vectors, encoding MUC-1 and CEA to human patients for treatment of tumors.

Applicants note that the Pecher reference indicates that CEA and/or MUC-1 are expressed by human tumors and *not* by one vector, as required by the pending claims. Specifically, the Pecher reference discloses a pharmaceutical composition comprising one vector (e.g., a plasmid) comprising the gene encoding MUC-1 and/or another vector (e.g., a plasmid) comprising the gene encoding CEA. Thus, CEA and MUC-1 are not in the same vector as required by the pending claims. Additionally, the Pecher reference does not identify CEA and/or MUC-1 as breast cancer associated antigens, or disclose the administration of a first and a second vector containing a DNA segment encoding CEA and MUC-1 to produce an immunological response against a cell expressing a breast cancer associated antigen in a human, as required by the pending claims.

Thus, none of the cited references, when considered alone or in combination, teaches or suggests inducing an immunological response against a cell expressing a breast cancer associated antigen by administering a first poxvirus vector containing one or more DNA segments that encode (i) CEA or an antigen portion thereof and (ii) MUC or an antigen portion thereof or a wobbled version thereof, and (c) at regular intervals thereafter administering at least a second poxvirus vector containing one or more DNA segments that encode (i) CEA or an antigen portion thereof and (ii) MUC or an antigenic portion thereof or a wobbled version thereof, as required by the claims.

Furthermore, as discussed in the previous Reply to Office Action, the inventive methods result in unexpected benefits, which further evidence the nonobviousness of the present invention, as defined by the pending claims, over the combination of the disclosures of the cited references. In particular, the inventive methods result in the beneficial effect of stimulating the immune system to target against the CEA and MUC-1 antigens. As a result, patients receiving this vaccine developed a significant increase in antigen-specific (MUC and CEA) immune response in patients and evidence of clinical benefit (see, e.g., Gulley et al., *Clin. Cancer Res., 14(10)*: 3060-3069 (2008), Tsang et al., *Clin. Cancer Res., 11*: 1597-1607

(2005); and Madan et al., *2007 Breast Cancer Symposium,* Abstract 237 (2007); and Mohebtash et al., *J. Clin. Oncol., 2008 ASCO Annual Meeting Proceedings 26:* 3035 (May 20, 2008)). (The Gulley and Tsang references are of record, and the Madan and Mohebtash references are submitted herewith.)

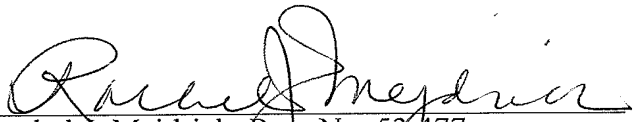
The benefits attendant the present invention are unexpected and surprising in view of the teachings in the art at the earliest priority date of the application. As evidenced by Palmowski et al. (*J. Immunol., 168*: 4391-4398 (2002); submitted herewith) and Brody et al. (*Immunol., 22*: 75-85 (1972); submitted herewith), prior to the invention, the presentation of two antigens together (at the same location) was thought to result in competition between the two antigens with one antigen being dominant, thereby resulting in a *reduced* immune response to one or both of the antigens (see, e.g., page 4397, second column, fourth full paragraph, of Palmowski et al., and page 83, lines 1-3, of Brody et al.).

For these reasons, the subject matter of the pending clams would not have been obvious to one of ordinary skill in the art at the relevant time in view of the combined disclosures of the Schlom and Pecher references. Accordingly, the obviousness rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



Rachel J. Mejdrich, Reg. No. 53,477
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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